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EXHIBIT A

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT INTERFERENCES

WALTER C. FIERs	)	
	)	
v.	)	
	)	
MICHEL REVEL and	)	
PIERRE TIOLLAIS	)	Interference No. 101,096
	)	
v.	)	
	)	
HARUO SUGANO ET AL.	)	

MOTION OF JUNIOR PARTY WALTER C. FIERs TO AMEND THE  
ISSUE BY SUBSTITUTION OF PROPOSED COUNT 2 FOR COUNT 1  
OR BY ADDITION OF PROPOSED COUNT 2 AND BY ADDITION OF  
PROPOSED COUNTS 3-9 PURSUANT TO 37 C.F.R. § 1.231(a)(2)  
AND TO BE ACCORDED THE BENEFIT OF THE FILING DATES OF HIS  
EARLIER UNITED KINGDOM PATENT APPLICATIONS WITH  
RESPECT TO THE SUBSTITUTED AND ADDED COUNTS PURSUANT  
TO 37 C.F.R. § 1.231(a)(4) AND (c)

Junior Party Walter C. Fiers moves under Rule 231(a)(2)  
[37 C.F.R. § 1.231(a)(2)] to amend the issue in this interference  
by substitution of proposed count 2 for Count 1, or by addition  
of proposed count 2, and by addition of proposed counts 3-9.  
Fiers also moves to be accorded for the subject matters of  
proposed counts 2-9 the benefit of the filing dates of his  
United Kingdom application 8011306, filed April 3, 1980, and  
his United Kingdom application 8018701, filed June 6, 1980.

Proposed Counts 2-9 are:

Proposed Count 2

A DNA sequence which consists essentially of a DNA  
which codes for a human fibroblast  $\beta_1$  interferon.

Proposed Count 3

A recombinant DNA molecule characterized by a DNA  
sequence which consists essentially of a DNA which  
codes for a human fibroblast  $\beta_1$  interferon, said  
DNA sequence being operatively linked to an expres-  
sion control sequence in the recombinant DNA mole-  
cule.

#### Proposed Count 4

A microbial host transformed with at least one recombinant DNA molecule, said recombinant DNA molecule being characterized by a DNA sequence which consists essentially of a DNA which codes for a human fibroblast  $\beta_1$  interferon, said DNA sequence being operatively linked to an expression control sequence in the recombinant DNA molecule.

#### Proposed Count 5

A human fibroblast  $\beta_1$  interferon produced by the method of culturing a microbial host transformed with a recombinant DNA molecule characterized by a DNA sequence which consists essentially of a DNA which codes for a human fibroblast  $\beta_1$  interferon, said DNA sequence being operatively linked to an expression control sequence in the recombinant DNA molecule.

#### Proposed Count 6

A method for producing a human fibroblast  $\beta_1$  interferon comprising the step of culturing a microbial host transformed with at least one recombinant DNA molecule, said recombinant DNA molecule being characterized by a DNA sequence which consists essentially of a DNA which codes for a human fibroblast  $\beta_1$  interferon, said DNA being operatively linked to an expression control sequence in the recombinant DNA molecule.

#### Proposed Count 7

A method for selecting a DNA sequence which codes for a human fibroblast  $\beta_1$  interferon from a group of DNA sequences comprising the step of determining which of said DNA sequences hybridizes to a DNA sequence which consists essentially of a DNA which codes for a human fibroblast  $\beta_1$  interferon.

#### Proposed Count 8

A composition for treating human viruses, treating human cancers or tumors, or useful in immunomodulation, comprising a pharmaceutically effective amount of at least one human fibroblast  $\beta_1$  interferon produced by the method of culturing a microbial host transformed with a recombinant DNA molecule characterized by a DNA sequence which consists essentially of a DNA which codes for a human fibroblast  $\beta_1$  interferon, said DNA sequence being operatively linked to an expression control sequence in the recombinant DNA molecule.

### Proposed Count 9

A method for treating human viruses, treating human cancers or tumors, or useful in immunomodulation, comprising the step of administering to humans in a pharmaceutically acceptable manner a pharmaceutically effective amount of a composition comprising a human fibroblast  $\beta_1$  interferon produced by the method of culturing a microbial host transformed with a recombinant DNA molecule characterized by a DNA sequence which consists essentially of a DNA which codes for a human fibroblast  $\beta_1$  interferon, said DNA sequence being operatively linked to an expression control sequence in the recombinant DNA molecule.

Proposed count 2 should be substituted for Count 1, or in the alternative added to this interference, because proposed count 2 is preferable to Count 1. It omits from Count 1 the term "polypeptide" which is unnecessary and may unreasonably complicate the proofs with respect to Count 1. Proposed count 2 also more correctly defines the DNA sequences of this interference in terms of a family of human fibroblast  $\beta_1$  interferons.

Proposed count 2 is patentable to junior party Fiers and appears in his application.\* It is "patentable" to Revel and Tiollais and to Sugano et al. and "supported" in their applications for the same alleged reasons that Count 1 is patentable to and supported by them.\*\*

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\* Fiers has concurrently herewith amended his United States patent application 250,609 to add, as claim 32, a claim that corresponds in all respects to proposed count 2. Fiers has appended hereto as Exhibit A a copy of that Amendment.

\*\* Fiers has moved concurrently herewith to dissolve this interference on the grounds that Count 1 is not patentable to Revel and Tiollais and not supported in their United States applications. See Motion Of Junior Party Walter C. Fiers To Dissolve This Interference Pursuant To 37 C.F.R. § 1.231(a)(1) As To Revel And Tiollais And To Deny To Revel And Tiollais The Benefit Of The Filing Date Of Their United States Patent Application 208,925 ("Fiers Motion To Dissolve-Revel And Tiollais").

Fiers has also moved to dissolve this interference because Count 1 is not patentable to Sugano et al. See Motion Of Junior Party Walter C. Fiers To Dissolve This Interference Pursuant To 37 C.F.R. § 1.231(a)(1) As To Sugano et al ("Fiers Motion To Dissolve-Sugano et al.").

Proposed counts 3-9 should be added to this interference because they are necessary to resolve all of the potential priority issues between the applications in interference. They involve different potential proofs. And they are patentably distinct from each other and the subject matter of Count 1 and proposed count 2. Each of proposed counts 3-9 is patentable to junior party Fiers and appears in his application.\* The other parties to this interference may also believe, and the Patent Examiner may find, that one or more of proposed counts 3-9 are patentable to them (which they are not), or supported by their applications (which they are not).

By this motion, junior party Fiers provides to Sugano et al. and to Revel and Tiollais the opportunity to attempt to demonstrate that one or more of proposed counts 3-9 are patentable to them and that their applications support one or more of those counts (which Fiers believes they cannot do). This motion also puts Sugano et al. and Revel and Tiollais on notice that junior party Fiers believes that the subject matters of proposed counts 3-9 are part of the invention that he has described and claimed in his application and that he intends to pursue the grant to him of United States patents describing and claiming the subject matters of proposed counts 3-9.

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\* Fiers has concurrently herewith amended his United States patent application 250,609 to add, as claims 33-39, claims that correspond in all respects to proposed counts 3-9. Fiers has appended hereto as Exhibit A a copy of that Amendment.

I. PROPOSED COUNT 2 SHOULD BE SUBSTITUTED  
FOR COUNT 1 OR IN THE ALTERNATIVE ADDED  
TO THIS INTERFERENCE

A. The Substitution Or Addition  
Of Proposed Count 2 To This  
Interference Is Necessary And  
Preferable

Count 1 did not originally appear in any of the United States patent applications now in interference. The Examiner suggested Count 1 for purposes of interference in Revel and Tiollais application 425,934 and in Sugano et al. application 201,359 on June 28, 1983. The Examiner subsequently suggested Count 1 for purposes of interference in Fiers application 250,609 on September 26, 1983.

Because Count 1 did not originally appear in any of the applications in interference, it contains a term -- "polypeptide" -- which is unnecessary and may unreasonably complicate the parties' proofs with respect to Count 1. Count 1 is also ambiguous with respect to whether or not it includes, as it should, DNA sequences that code for the family of human fibroblast  $\beta_1$  interferons. Proposed count 2 avoids each of these potential difficulties. Accordingly, it should be substituted for Count 1, or in the alternative added to this interference.

Proposed count 2 omits the unnecessary term "polypeptide" from Count 1. Count 1 defines a DNA sequence that codes for a product of specified activity -- a human fibroblast  $\beta_1$  interferon. For purposes of this interference no further characterization of that interferon activity is required. The omission of the term "polypeptide" from Count 1 also avoids potential objections to the parties' disclosures and proofs that the human fibroblast  $\beta_1$  interferon coded for by the claimed DNA sequence is a polypeptide. For example, the term "polypeptide"

could arguably require an actual determination of the complete amino acid sequence of a human fibroblast  $\beta_1$  interferon and, perhaps, a demonstration that the bonds between the various amino acids are peptide bonds. It could also arguably require a demonstration that the product is sensitive to proteases. Because the term "polypeptide" is unnecessary, a requirement for these proofs is also not appropriate.

Proposed count 2 also avoids the ambiguity of Count 1 by reciting that the DNA sequence codes for "a" human fibroblast  $\beta_1$  interferon. Accordingly, proposed count 2 acknowledges that the recited human fibroblast  $\beta_1$  interferon is actually a family of products.\* It also avoids difficult to resolve disputes of whether one or more amino acid additions or deletions from native human fibroblast  $\beta_1$  interferon in an interferon coded for by the recited DNA sequence take that product out of the scope of Count 1. Accordingly, proposed count 2's recitation of a genus of human fibroblast  $\beta_1$  interferons is also necessary and preferable for contesting the priority issues in interference.

B. Proposed Count 2 Is Patentable To Junior Party Fiers And Appears In His Application

Proposed count 2 is patentable to junior party Fiers and appears in Fiers United States application 250,609.\*\*

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\* Fiers has demonstrated that several different products have the activity of a human fibroblast  $\beta_1$  interferon. For example, Fiers produced "mature" fibroblast  $\beta_1$  interferon as the active product of G-pPLA-HFIF-67-12 $\Delta$ M1 and G-pHLA-HFIF-67-12 $\Delta$ 19 BX-2 [page 88, lines 19-22]. Fiers also produced possible fusion products that had IFN- $\beta_1$  activity from G-pPLA-HFIF-67-12 $\Delta$ 19 and pPLc-HFIF-67-8 [page 88, lines 22-31].

\*\* Fiers has concurrently herewith amended his United States patent application 250,609 to add, as claim 32, a claim that corresponds in all respects to proposed count 2. Fiers has appended hereto as Exhibit A a copy of that Amendment.

Proposed count 2 is specifically supported by Fiers application 250,609 for the same reasons as Count 1 is supported by that application. For example, Fiers described a DNA sequence for the "coding strand of IFN- $\beta$  DNA" [page 48, line 36-page 49, line 2; Figure 4] and disclosed that the DNA sequence was capable of directing the production of "polypeptides displaying an immunological or biological activity of HuIFN- $\beta$ " [page 12, lines 22-23; page 77, line 31-page 88, line 35]. Fiers also identified and deposited in recognized culture collections before the filing date of that application specific DNA sequences that coded for and produced a human fibroblast  $\beta_1$  interferon. For example, Fiers identified and deposited E.coli HB101(G-pBR322(Pst)/HFIF3, 6 and 7) that contained DNA sequences from which a DNA sequence that codes for a human fibroblast  $\beta_1$  interferon is produced [page 94, lines 13-22]. Fiers also described using that DNA sequence and its derivatives to produce various human fibroblast  $\beta_1$  interferons [e.g., page 77, line 31-page 88, line 35] and Fiers deposited in recognized culture collections specific DNA sequences that produced those  $\beta_1$  interferons [page 94, line 23-page 95, line 2].\*

Proposed count 2 is patentable to Fiers for the same reasons that Count 1 is patentable to him. There is no document of record in Fiers United States application 250,609, or in any of the other applications in interference, having an effective date before April 3, 1980 or June 6, 1980 (the filing dates of the Fiers United Kingdom patent applications 8011306 and 8018701 to which he is entitled for the subject

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\* For example, Fiers produced "mature" fibroblast  $\beta_1$  interferon as the active product of G-pPLa-HFIF-67-12 $\Delta$ M1 (ATCC 31824) and G-pPLa-HFIF-67-12 $\Delta$ 19 BX-2 [page 88, lines 19-22]. Fiers also produced possible fusion products that had fibroblast  $\beta_1$  interferon activity from G-pPLa-HFIF-67-12 $\Delta$ 19 (DSM 1853) and pPLc-HFIF-67-8 (DSM 1854) [page 88, lines 22-31].



matter of Count 1) that describes or suggests that subject matter. See Motion Of Junior Party Walter C. Fiers To Be Accorded The Benefit Of The Filing Dates Of His Earlier United Kingdom Patent Applications Pursuant To 37 C.F.R. §§ 1.224 and 1.231(a)(4) And To Shift The Burden Of Proof Under 37 C.F.R. § 1.257(a) ("Fiers Motion-Count 1"). The deletion of the term "polypeptide" in proposed count 2 and its avoidance of the former "ambiguity" of Count 1 does not affect the novelty and unobviousness of the subject matter of that count to Fiers.

C. Proposed Count 2 And The Sugano et al.  
And Revel And Tiollais United States  
Applications

Proposed count 2 is "supported" in the Sugano et al. United States application for the same alleged reasons as Count 1. Sugano et al. United States application 201,359 refers to "a DNA which codes for a human fibroblast interferon polypeptide" and recites in Table 5 a base sequence for that DNA [page 8, lines 12-13]. It also recites that a DNA sequence (T<sub>p</sub>IF-319-13) was deposited on September 16, 1980 in a culture collection. However, proposed count 2 is not patentable to Sugano et al. for the same reasons that Count 1 is not patentable to them.\* Should Sugano et al. be successful in demonstrating the patentability to themselves of Count 1 (which they should not be able to do), proposed count 2 should be substituted for Count 1, or in the alternative added to this interference.

Proposed count 2 is not "supported" in the Revel and Tiollais United States applications and not "patentable to" them for the same reasons that Count 1 is not supported

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\* Fiers has moved concurrently herewith to dissolve this interference because Count 1 is not patentable to Sugano et al. See Fiers Motion To Dissolve-Sugano et al.

by or patentable to them.\* However, should Revel and Tiollais be successful in demonstrating that their United States applications support Count 1 and that Count 1 is patentable to them (which they should not be able to do), proposed count 2 should be substituted for Count 1, or in the alternative added to this interference.

II. PROPOSED COUNTS 3-9 SHOULD BE ADDED  
TO THIS INTERFERENCE

A. The Addition Of Proposed  
Counts 3-9 To This Interference  
Is Necessary And Preferable

The addition of proposed counts 3-9 to this interference is necessary and preferable in order to resolve all of the potential priority issues between the applications in interference in a single interference proceeding.

Each of the United States applications in interference originally recited various groups of claims. During their initial prosecutions, the respective Patent Examiners made multiple restriction requirements in each application among these groups of claims [Sugano et al. application 201,359, Paper No. 3, November 3, 1981; Revel and Tiollais application 208,925, Paper No. 3, November 17, 1981; Fiers application 250,609, Examiner's Action, April 15, 1982]. For example, the Examiners divided the applications among claims drawn to DNA and claims drawn to plasmids and hosts [Sugano et al., Paper No. 3, p. 2]; among claims drawn to DNA, claims drawn to methods of detecting DNA, claims drawn to recombinant DNA molecules, and claims drawn to interferons [Revel and

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\* Fiers has moved concurrently herewith to dissolve this interference with respect to Revel and Tiollais on both of those grounds. See Fiers Motion To Dissolve-Revel and Tiollais.

Tiollais, Paper No. 3, p. 2]; and among claims drawn to DNA, claims drawn to interferons, claims drawn to methods of producing interferons, claims drawn to methods of detecting DNA and claims drawn to methods of treating viruses and cancers [Fiers, Examiner's Action, p. 2]. In support of these restriction requirements, the Examiners contended that the various groups of claims were "distinct" and could support "separate patents".

In response to these restriction requirements, each of the applicants elected claims for initial prosecution and withdrew the non-elected claims from prosecution. Accordingly, each of the applications has claims that are not now in interference and which the Examiners have held to be "distinct" and able to support "separate patents". It is these groups of claims that Fiers has moved to add to this interference.\*

Proposed counts 3-9 are patentably distinct from each other and from Count 1 and proposed count 2 [See United States Patent and Trademark Office, Manual of Patenting Examining Procedure (5th ed. August 1983) § 1105.03]. They also represent subject matter on which different proofs of "invention" and "priority" are likely to be offered by each of the parties. For example, the recombinant DNA molecule of proposed count 3 will require different proofs from the DNA of Count 1 because the recombinant DNA molecule must be capable of expressing a human fibroblast  $\beta_1$  interferon. And the DNA selection method of proposed count 7 will require different proofs from the interferon of proposed count 5.

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\* For example, the human fibroblast  $\beta_1$  interferon of proposed count 5 was in Fiers Group II, the method of proposed count 6 in Fiers Group III, the method of proposed count 7 in Fiers Group IV and the method of proposed count 9 in Fiers Group V.

Plainly, a single interference should resolve all of the potential priority issues between these applications. Judicial economy demands nothing less. So does the possibility of interference estoppel that may affect junior or losing parties to an interference [e.g., Stoudt v. Guggenheim, 651 F.2d 760, 210 USPQ 359 (CCPA 1981); In re Hoover Co., 134 F.2d 624, 57 USPQ 111 (CCPA 1943); In re Allsop, 26 F.2d 559 (D.C.Cir. 1928); Blackford v. Wilder, 28 App. D.C. 535, 1907 C.D. 491, 127 O.G. 1255 (1907); Ex parte Miller, 124 USPQ 419 (PO Bd App 1959); Ex parte Voris, 92 USPQ 47 (PO Bd App 1951); 37 C.F.R. § 1.257 (1983)]. Therefore, proposed counts 3-9 should be added here. However, they should not be added to this interference unless, and until, the Patent Examiner finds that the proposed counts are patentable to either Sugano et al. or Revel and Tiollais (which they are not) and are supported by their applications (which they are not) [infra, pp. 13-15].

B. Proposed Counts 3-9 Are Patentable To Junior Party Fiers And Appear In His Application

Proposed counts 3-9 are patentable to junior party Fiers and appear in his United States patent application 250,609.\*

Proposed counts 3-9 are specifically supported by Fiers application 250,609. For example, Fiers described a DNA sequence for the "coding strand of IFN- $\beta$  DNA" [page 48, line 36-page 49, line 2; Figure 4] and disclosed that the DNA sequence was capable when operatively linked to an expression control sequence in a recombinant DNA molecule of directing

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\* Fiers has concurrently herewith amended his United States patent application 250,609 to add, as claims 33-39, claims that correspond in all respects to proposed counts 3-9. Fiers has appended hereto as Exhibit A a copy of that Amendment.

the production of "polypeptides displaying an immunological or biological activity of HuIFN- $\beta$ " in microbial hosts transformed with that recombinant DNA molecule [page 12, lines 22-23; page 77, line 31-page 88, line 35]. Fiers also identified and deposited in recognized culture collections recombinant DNA molecules characterized by DNA sequences that code for a human fibroblast  $\beta_1$  interferon and are operatively linked to expression control sequences (proposed count 3), and microbial hosts transformed with those recombinant DNA molecules (proposed count 4) that produced a human fibroblast  $\beta_1$  interferon after fermentation (proposed counts 5 and 6) [page 94, line 22-page 95, line 2].

Fiers also disclosed using his DNA sequences that coded for a human fibroblast  $\beta_1$  interferon to select by hybridization other DNA sequences that coded for a human fibroblast  $\beta_1$  interferon (proposed count 7) [e.g., page 44, lines 26-page 47, line 15; page 92, line 31-page 94, line 12]. And Fiers disclosed using his human fibroblast  $\beta_1$  interferons in compositions (proposed count 8) and methods (proposed count 9) for treating human viruses, treating human cancers or tumors, or in immunomodulation [e.g., page 4, line 11-page 7, line 15; page 12, lines 29-35].

Finally, Fiers originally claimed the subject matter of proposed counts 3-9 in his United States application. Compare proposed count 3 with Fiers claims 7-10; proposed count 4 with Fiers claim 11 (as it depends from claims 7-10) and claims 12-15; proposed count 5 with Fiers claims 16 and claims 18-19 (as they depend from claim 16); proposed count 6 with Fiers claim 25; proposed claim 7 with Fiers claims 26-27; proposed count 8 with Fiers claim 28 and; proposed count 9 with Fiers claim 29.

As we have demonstrated, proposed counts 3-9 are supported in the Fiers United States application. They are also patentable to him. None of the documents of record in Fiers United States application 250,609, or in any of the other United States applications in interference, described or suggested the production of a human fibroblast  $\beta_1$  interferon in a microbial host before the dates to which Fiers is entitled for proposed counts 3-9 [*infra*, pp. 15-18]. None suggested or described any recombinant DNA molecule characterized by a DNA sequence which consists essentially of a DNA which codes for a human fibroblast  $\beta_1$  interferon, which DNA is operatively linked to an expression control sequence in the recombinant DNA molecule (proposed count 3) or any microbial host transformed with that recombinant DNA molecule (proposed count 4). None suggested or described using those microbial hosts to produce a human fibroblast  $\beta_1$  interferon by fermentation (proposed count 6), the interferon produced by that method (proposed count 5), or methods or compositions employing that interferon against viruses, cancer and tumors, or in immunomodulation (proposed counts 8-9). Furthermore, none suggested or described using that IFN- $\beta_1$  DNA sequence to select other DNA sequences that also code for a human fibroblast  $\beta_1$  interferon by hybridization (proposed count 7).

C. Proposed Counts 3-9 And The Sugano  
et al. And Revel And Tiollais  
United States Applications

Neither Sugano et al. United States patent application 201,359, nor Revel and Tiollais United States patent application 208,925, supports the subject matter of proposed counts 3-9.

Neither Sugano et al. nor Revel and Tiollais described any recombinant DNA molecule characterized by a DNA sequence

consisting essentially of a DNA coding for a human fibroblast  $\beta_1$  interferon which is operatively linked to an expression control sequence in the recombinant DNA molecule (proposed count 3) or any microbial host transformed with that recombinant DNA molecule (proposed count 4). Neither described using a microbial host to produce a human fibroblast  $\beta_1$  interferon by fermentation (proposed count 6), any interferon produced by that method (proposed count 5), or any method or composition for employing that interferon against viruses, cancers or tumors, or in immunodulation (proposed counts 8-9). And neither described using that DNA sequence to select other DNA sequences that code for a human fibroblast  $\beta_1$  interferon (proposed count 7). Furthermore, neither Sugano et al. nor Revel and Tiollais deposited in a culture collection any recombinant DNA molecule or microbial host that produced a human fibroblast  $\beta_1$  interferon. Accordingly, neither is entitled to make claims corresponding to proposed counts 3-9.

Sugano et al. implicitly concedes that they have no right to make claims corresponding to proposed counts 3-9 by not claiming that subject matter in their United States application 201,359. Revel and Tiollais United States application 208,925 does "claim" a process for "engineering a bacterial strain to produce interferon polypeptide" using a "suitable vector-carrier" (Revel and Tiollais claims 9-11) and the "interferon" produced by that process (Revel and Tiollais claims 24, 43-44). However, neither of those classes of claims is supported in any way in Revel and Tiollais' United States applications. See Fiers Motion To Dissolve-Revel And Tiollais. Accordingly, neither Sugano et al. nor Revel and Tiollais are entitled to contest the priority of the subject matter of proposed counts 3-9.

Although junior party Fiers does not believe that Sugano et al. or Revel and Tiollais can make any claim corresponding to proposed counts 3-9, Fiers has by this motion given to each of them the opportunity to demonstrate their "support" for the subject matters of those proposed counts and the "patentability" of those proposed counts to themselves. Fiers has also put each of them on notice that he intends to pursue the grant of United States patents describing and claiming the subject matters of proposed counts 3-9.

III. FIERS SHOULD BE ACCORDED THE BENEFIT OF THE FILING DATES OF HIS EARLIER UNITED KINGDOM PATENT APPLICATIONS FOR PROPOSED COUNTS 2-9 AND SHOULD BE SENIOR PARTY WITH RESPECT TO THOSE PROPOSED COUNTS

Junior party Fiers moves under Rule 224 and 231(a)(4) [37 C.F.R. §§ 1.224 and 1.231(a)(4)] to be accorded the benefit of the filing dates of his earlier United Kingdom patent applications for the subject matter of proposed counts 2-9 and to be accorded senior party status with respect to those proposed counts under Rule 257(a) [37 C.F.R. § 1.257(a)].

A. Fiers Is Entitled To The Benefit Of The April 3, 1980 Filing Date Of His United Kingdom Patent Application 8011306 For The Subject Matters Of Proposed Counts 2 and 7

Fiers United Kingdom patent application 8011306 describes and enables the subject matter of proposed count 2 for the same reasons that it describes and enables the subject matter of Count 1.\* See Fiers Motion-Count 1, pp. 2-6. The differences between Count 1 and proposed count 2 do not change in any way Fiers' specific support for that subject matter.

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\* A certified copy of that application was of record in Fiers United States application 250,609 at the time this interference was declared. Accordingly, it is not submitted here. See 37 C.F.R. § 1.224.



Fiers United Kingdom patent application 8011306 also supports proposed count 7. It described and claimed a method for using a DNA sequence that consisted essentially of DNA coding for a human fibroblast  $\beta_1$  interferon to select other DNA sequences coding for a human fibroblast  $\beta_1$  interferon by hybridization (proposed count 7). See, e.g., page 40, line 1-page 42, line 14; claims 12-14.

Fiers previously claimed priority from that United Kingdom application in his United States application 250,609 and made a certified copy of it of record there. Nothing else needs to be done for Fiers to be entitled to the filing date of that application for the subject matters of proposed counts 2 and 7.

B. Fiers Is Entitled To The Benefit Of  
The June 6, 1980 Filing Date Of His  
United Kingdom Patent Application  
8018701 For The Subject Matters Of  
Proposed Counts 2 and 7

Fiers United Kingdom patent application 8018701 describes and enables the subject matter of proposed count 2 for the same reasons that it describes and enables the subject matter of Count 1.\* See Fiers Motion-Count 1, pp. 6-8.

Fiers United Kingdom patent application 8018701 also described and claimed a method for using a DNA sequence that consisted essentially of DNA coding for a human fibroblast  $\beta_1$  interferon to select other DNA sequences coding for a human fibroblast  $\beta_1$  interferon by hybridization (proposed count 7). See, e.g., page 42, line 1-page 44, line 18; claims 12-14.

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\* A certified copy of that application was of record in Fiers United States application 250,609 at the time this interference was declared. Accordingly, it is not submitted here. See 37 C.F.R. § 1.224.

Fiers previously claimed priority from that United Kingdom application in his United States application 250,609 and made a certified copy of it of record there. Nothing else needs to be done for Fiers to be entitled to the filing date of that application for the subject matters of proposed counts 2 and 7.

C. Fiers Is Entitled To The Benefit Of  
The June 6, 1980 Filing Date Of His  
United Kingdom Patent Application  
8018701 For The Subject Matters Of  
Proposed Counts 3-6 And 8-9

Fiers United Kingdom patent application 8018701 describes and enables the subject matters of proposed counts 3-6 and 8-9. It also sets forth the best mode contemplated by Fiers for practicing those subject matters. Accordingly, Fiers should be accorded for the subject matters of proposed counts 3-6 and 8-9 the benefit of his June 6, 1980 filing date of United Kingdom patent application 8018701.\*

United Kingdom patent application 8018701, filed June 6, 1980, described recombinant DNA molecules characterized by a DNA sequence which consisted essentially of a DNA that codes for a human fibroblast  $\beta_1$  interferon and which was operatively linked to an expression control sequence in those recombinant DNA molecules (proposed count 3) [page 54, line 1-page 60, line 11]. It described microbial hosts transformed with those recombinant DNA molecules (proposed count 4) that produced a human fibroblast  $\beta_1$  interferon after fermentation (proposed counts 5 and 6) [page 61, line 1-page 76, line 26]. The application also described using the produced human fibroblast  $\beta_1$

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\* Fiers has not attached to this motion a copy of his United Kingdom application 8018701. A certified copy of the application was of record in Fiers United States application 250,609 at the time this interference was declared. See 37 C.F.R. § 1.224.

interferon in compositions (proposed count 8) and methods (proposed count 9) for treating human viruses and cancers or tumors [page 5, line 3-page 7, line 25; page 11, lines 30-35].

Fiers United Kingdom application 8018701 also recited the deposit in a recognized culture collection of recombinant DNA molecules characterized by a DNA sequence that consisted essentially of a DNA that coded for a human fibroblast  $\beta_1$  interferon which was operatively linked to an expression control sequence in that recombinant DNA molecule, and microbial hosts transformed with those recombinant DNA molecules that produced a human fibroblast  $\beta_1$  interferon upon fermentation [page 81, lines 10-19].

Finally, Fiers United Kingdom application 8018701 originally claimed the subject matter of proposed counts 3-6 and 8-9. Compare, e.g., proposed count 3 with Fiers claims 22, 25 and 26; proposed count 4 with Fiers claims 27-28 (as they depend from claims 22, 25 and 26) and claim 29; proposed count 5 with Fiers claim 32 (as it depends from claims 22, 25 and 26); proposed count 6 with Fiers claims 39 and 40; proposed count 8 with Fiers claims 35 and 37 (as they depend from claims 22, 25 and 26) and claim 36 (as it depends from claim 32); and proposed count 9 with Fiers claims 41-43 (as they depend from claims 22, 25 and 26) and claims 42 and 44 (as they depend from claim 32).

For all of those reasons, Fiers is entitled to the benefit of the June 6, 1980 filing date of his United Kingdom patent application 8018701 for the subject matters of proposed counts 3-6 and 8-9.

#### IV. CONCLUSION

Proposed count 2 should be substituted for Count 1, or in the alternative added to this interference. It is pre-

ferable to Count 1 and necessary to avoid the ambiguity of Count 1 and the possible objections to the parties' applications and proofs with respect to Count 1. If proposed count 2 is added to this interference, or substituted for Count 1, Fiers is entitled to the April 3, 1980 filing date of his United Kingdom patent application 8011306 and to the June 6, 1980 filing date of his United Kingdom patent application 8018701 for the subject matter of that proposed count. Accordingly, Fiers is senior party with respect to proposed count 2.

Proposed counts 3-9 should be added to this interference if, and only if, the Examiner finds that Sugano et al. or Revel and Tiollais support them (which they do not) and that the proposed counts are patentable to them (which they are not).

If any of the proposed counts 3-9 is added to this interference, Fiers is entitled to the filing dates of his earlier United Kingdom patent applications for their subject matters. He is entitled to the April 3, 1980 filing date of his United Kingdom patent application 8011306 and to the June 6, 1980 filing date of his United Kingdom patent application 8018701 for the subject matter of proposed count 7. He is entitled to the June 6, 1980 filing date of his United Kingdom patent application 8018701 for the subject matters of proposed counts 3-6 and 8-9. Accordingly, Fiers is senior party with respect to each of proposed counts 3-9.

Respectfully submitted,



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James F. Haley, Jr.

Signature of Person Signing Certificate  
20 July 1980

Date of Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : J. Martinell  
Group Art Unit : 127  
Applicant : Walter C. Fiers  
Serial No. : 250,609  
Filed : April 3, 1981  
For : DNA SEQUENCES, RECOMBINANT DNA  
MOLECULES AND PROCESSES FOR  
PRODUCING HUMAN FIBROBLAST  
INTERFERON-LIKE POLYPEPTIDES

Exhibit A

New York, New York  
July 20, 1984

Hon. Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

AMENDMENT

Sir:

In accordance with Rule 231(c) [37 C.F.R. § 1.231(c)],  
kindly amend the above-identified patent application as follows:

IN THE CLAIMS

Add Claims 32-39:

32. A DNA sequence which consists essentially of a  
DNA which codes for a human fibroblast  $\beta_1$  interferon.

33. A recombinant DNA molecule characterized by a  
DNA sequence which consists essentially of a DNA which codes  
for a human fibroblast  $\beta_1$  interferon, said DNA sequence being  
operatively linked to an expression control sequence in the  
recombinant DNA molecule.

34. A microbial host transformed with at least one  
recombinant DNA molecule, said recombinant DNA molecule being

characterized by a DNA sequence which consists essentially of a DNA which codes for a human fibroblast  $\beta_1$  interferon, said DNA sequence being operatively linked to an expression control sequence in the recombinant DNA molecule.

35. A human fibroblast  $\beta_1$  interferon produced by the method of culturing a microbial host transformed with a recombinant DNA molecule characterized by a DNA sequence which consists essentially of a DNA which codes for a human fibroblast  $\beta_1$  interferon, said DNA sequence being operatively linked to an expression control sequence in the recombinant DNA molecule.

36. A method for producing a human fibroblast  $\beta_1$  interferon comprising the step of culturing a microbial host transformed with at least one recombinant DNA molecule, said recombinant DNA molecule being characterized by a DNA sequence which consists essentially of a DNA which codes for a human fibroblast  $\beta_1$  interferon, said DNA sequence being operatively linked to an expression control sequence in the recombinant DNA molecule.

37. A method for selecting a DNA sequence which codes for a human fibroblast  $\beta_1$  interferon from a group of DNA sequences comprising the step of determining which of said DNA sequences hybridizes to a DNA sequence which consists essentially of a DNA which codes for a human fibroblast  $\beta_1$  interferon.

38. A composition for treating human viruses, treating human cancers or tumors, or useful in immunomodulation, comprising a pharmaceutically effective amount of at least one human fibroblast  $\beta_1$  interferon produced by the method of culturing a microbial host transformed with a recombinant DNA

molecule characterized by a DNA sequence which consists essentially of a DNA which codes for a human fibroblast  $\beta_1$  interferon, said DNA sequence being operatively linked to an expression control sequence in the recombinant DNA molecule.

39. A method for treating human viruses, treating human cancers or tumors, or useful in immunomodulation, comprising the step of administering to humans in a pharmaceutically acceptable manner a pharmaceutically effective amount of a composition comprising a human fibroblast  $\beta_1$  interferon produced by the method of culturing a microbial host transformed with a recombinant DNA molecule characterized by a DNA sequence which consists essentially of a DNA which codes for a human fibroblast  $\beta_1$  interferon, said DNA sequence being operatively linked to an expression control sequence in the recombinant DNA molecule.

#### REMARKS

Applicant has added Claims 32-39 to this application for purposes of possible interference in connection with his July 20, 1984 motion to substitute and to add proposed counts 2-9 (Claims 32-39) to the Fiers v. Revel and Tiollais v. Sugano et al., Interference No. 101,096 [37 C.F.R. § 1.231(c)].\*

Claims 32-39 are supported in this application. Their subject matter was described and claimed in the application as filed. For example, the application identified, described and deposited a DNA sequence coding for human fibroblast  $\beta_1$  interferon (Claim 32) and described and claimed using that DNA sequence in a hybridization-based method for selecting DNA sequences that code for a human fibroblast  $\beta_1$

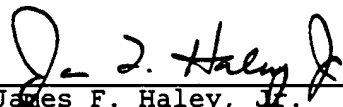
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\* Applicant has attached a copy of this Amendment to his motion to substitute and to add these proposed counts and has served it on the two other parties to the interference.

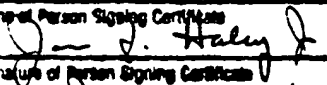
interferon (Claim 37). See, e.g., page 18, line 14-page 52, line 18; page 52, line 19-page 88, line 35; page 92, line 31-page 94, line 12; page 94, lines 13-22; page 94, line 22-page 95, line 2; Figures 4 and 5; claims 5 and 26. It also described and deposited recombinant DNA molecules and microbial hosts transformed with them that were characterized by a DNA sequence which codes for a human fibroblast  $\beta_1$  interferon and which is operatively linked to an expression control sequence in the recombinant DNA molecule (Claims 33-34). See, e.g., page 52, line 19-page 88, line 35; page 94, line 22-page 95, line 2; Figures 8-13; claims 7-15. This application also described and claimed a human fibroblast  $\beta_1$  interferon produced by culturing those transformed microbial hosts and a method for that  $\beta_1$  interferon's production (Claims 35-36). See, e.g., page 67, line 22-page 88, line 35; Figure 4; claims 16-19 and 25. Finally, the application described and claimed methods and compositions for treating human viruses, treating human cancers or tumors, or useful in immunomodulation, using those human fibroblast  $\beta_1$  interferons (Claims 38-39). See, e.g., page 12, lines 29-35; claims 28-29.

Applicant requests entry of Claims 32-39 for the purposes of possible interference.

Respectfully submitted,

  
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JAMES F. HALEY JR.  
 Name of Person Signing Certificate  
  
 Signature of Person Signing Certificate  
July 20, 1984  
 Date of Signature



CERTIFICATE OF SERVICE

I, James F. Haley, Jr., certify that on the 20th day of July, 1984, I served the attached MOTION OF JUNIOR PARTY WALTER C. FIERs TO AMEND THE ISSUE BY SUBSTITUTION OF PROPOSED COUNT 2 FOR COUNT 1 OR BY ADDITION OF PROPOSED COUNT 2 AND BY ADDITION OF PROPOSED COUNTS 3-9 PURSUANT TO 37 C.F.R. § 1.231(a)(2) AND TO BE ACCORDED THE BENEFIT OF THE FILING DATES OF HIS EARLIER UNITED KINGDOM PATENT APPLICATIONS WITH RESPECT TO THE SUBSTITUTED AND ADDED COUNTS PURSUANT TO 37 C.F.R. § 1.231(a)(4) AND (c) on party Sugano et al. and on party Revel and Tiollais, by causing one true copy of same to be deposited with the United States Postal Service, first class mail, postage prepaid, addressed, respectively, to counsel for Sugano et al.:

Joseph M. Fitzpatrick, Esq.  
Nels T. Lippert, Esq.  
Fitzpatrick, Cella, Harper & Scinto  
277 Park Avenue  
New York, New York 10172

and to counsel for Revel and Tiollais:

Alvin Browdy, Esq.  
Roger L. Browdy, Esq.  
Browdy and Neimark  
419 7th Street, N.W.  
Washington, D.C. 20004

  
James F. Haley, Jr.

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